Presidential Advisory Council on HIV/AIDS (PACHA)
68th Meeting (Virtual)

August 6, 2020

Council Members—Present

Carl Schmid, M.B.A., PACHA Co-Chair, Executive Director, HIV + Hepatitis Policy Institute, Washington, DC
John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chair, Secretary of Health, Washington State Department of Health, Olympia, WA
Alicia Diggs, M.P.H., Medical Case Manager, Positive Wellness Alliance, Lexington, NC
Vincent Guillamo-Ramos, Ph.D., M.P.H., LCSW, ACRN, ANP-BC, AAHIVS, Professor and Director, Center for Latino Adolescent and Family Health, New York University (NYU); Pilot and Mentoring Core Director, Center for Drug Use and HIV Research, NYU; Nurse Practitioner, Adolescent AIDS Program, Montefiore Medical Center, Bronx, NY
Wendy Holman, CEO and Co-Founder, Ridgeback Biotherapeutics, Miami, FL
Rafaelé Narváez, Co-Founder and Director of Health Programs, Latinos Salud, Wilton Manors, FL
Laura Platero, J.D., Executive Director, Northwest Portland Area Indian Health Board, Portland, OR
Michael Saag, M.D., Associate Dean, Global Health, School of Medicine, and Professor of Medicine, Division of Infectious Disease, University of Alabama at Birmingham (UAB); Director, UAB Center for AIDS Research, Birmingham, AL
John Sapero, Director, Ending the HIV Epidemic, Collaborative Research LLC, Phoenix, AZ
Robert A. Schwartz, M.D., M.P.H., D.Sc. (Hon.), Professor and Head, Dermatology, Rutgers New Jersey Medical School, Rutgers, The State University of New Jersey, Newark, NJ
Justin C. Smith, M.S., M.P.H., Director, Campaign to End AIDS, Positive Impact Health Centers; Behavioral Scientist, Rollins School of Public Health, Emory University, Atlanta, GA
Ada Stewart, M.D., RPh, FAAFP, AAHIVS, HMDC, Lead Provider and HIV Specialist, Eau Claire Cooperative Health Centers (Now Cooperative Health), Columbia, SC

Council Members—Absent

Gregg H. Alton, J.D., San Francisco, CA
Marc Meachem, M.B.A., Head, External Affairs, ViiV Healthcare North America, Washington, DC

Liaison: Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and Sexually Transmitted Disease (STD) Prevention and Treatment

Jennifer Kates, Ph.D., Senior Vice President and Director, Global Health and HIV Policy, Kaiser Family Foundation

Staff

B. Kaye Hayes, M.P.A., PACHA Executive Director, Designated Federal Officer; Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS)
Caroline Talev, M.P.A., Public Health Analyst and PACHA Committee Manager, OIDP, OASH, HHS

Federal Partners

William Chang, Deputy General Counsel, Office of the General Counsel, HHS
Laura Cheever, M.D., Sc.M., Associate Administrator, HIV/AIDS Bureau, HRSA
Antigone Dempsey, M.Ed., Director, Division of Policy and Data, HIV/AIDS Bureau, HRSA
Dorothy Fink, M.D., Director, Office of Women's Health, HHS
Neeraj Gandotra, M.D., Chief Medical Officer, Substance Abuse and Mental Health Services Administration
ADM Brett P. Giroir, M.D., U.S. Public Health Service (USPHS), Assistant Secretary for Health (ASH), HHS
Maureen M. Goodenow, Ph.D., Associate Director for AIDS Research, Director, Office of AIDS Research, National Institutes of Health (NIH)
Rita Harcrow, Director, Office of HIV/AIDS Housing, U.S. Department of Housing and Urban Development
Rick Haverkate, M.P.H., National HIV/AIDS & Hepatitis C Program Coordinator, Indian Health Service (IHS)
David Johnson, Deputy ASH, OASH, HHS
Eugene McCray, M.D., Director, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP), CDC
RADM Jonathan Mermin, M.D., M.P.H., USPHS, Director, NCHHSTP, CDC
Douglas Olson, M.D., Chief Medical Officer, Medicaid/Children's Health Insurance Program, Centers for Medicare & Medicaid Services (CMS)
Harold J. Philips, Senior HIV Advisor and Chief Operating Officer, *Ending the HIV Epidemic: A Plan for America* (EHE), OASH, HHS
Crystal Simpson, M.D., Medical Officer, Office of Medicare, CMS, HHS
Judith Steinberg, M.D., M.P.H., Chief Medical Officer, OIDP
RADM Michael Toedt, M.D., Chief Medical Officer, IHS
RADM Sylvia Trent-Adams, Ph.D., RN, FAAN, Acting Director, OIDP; Principal Deputy ASH, HHS
CAPT Samuel Wu, Pharm.D., Public Health Advisor, Office of Minority Health, HHS
Sara Ziegler, Associate Director for Planning and Policy, NCHHSTP, CDC

Welcome and Remarks from the Co-Chairs

John Wiesman, Dr.P.H., M.P.H., PACHA Co-Chair, called the meeting to order at 3:01 p.m. (This meeting was broadcast live online; the recorded broadcast is available online at https://www.youtube.com/watch?v=xVw9-Hj8k5c&feature=youtu.be.) The goal of this meeting

was to swear in a new member and to consider three resolutions from PACHA subcommittees, two of which reflect topics discussed at the June 1–2, 2020, virtual PACHA meeting.

Carl Schmid, M.B.A., PACHA Co-Chair, noted that the Federal government continues to focus on the EHE initiative. CDC recently distributed $109 million to jurisdictions to begin their EHE efforts. Mr. Schmid pointed out that the President proposed $450 million for the second year of EHE, but the House proposed only $65 million, and the Senate has not yet weighed in. He added that organizations across the country hope to ramp up EHE activities, but funding is needed to support them.

Welcome and Swearing-In of New PACHA Member

ADM Brett P. Giroir, M.D., USPHS, ASH, HHS

ADM Giroir expressed condolences for those who have suffered and died from COVID-19 and HIV/AIDS. He thanked all those working in public health and serving people with HIV (PWH) for their continued dedication. ADM Giroir emphasized that EHE remains a priority for him, HHS Secretary Alex Azar, and Surgeon General Jerome Adams, M.D.

ADM Giroir said HHS will continue to expand access to preexposure prophylaxis (PrEP) at no cost to people without prescription drug coverage through the Ready, Set, PrEP (RSP) program. He announced a new, long-term contract with TrialCard, which will verify participant eligibility, enroll eligible individuals, maintain the network of participating pharmacies, distribute the donated medications to uninsured participants, and process requests for the distributed medications. TrialCard will be responsible for new and current enrollees beginning November 1, 2020.

On August 17, 2020, ADM Giroir explained, HHS will launch a dashboard for HIV epidemiologic analysis to support EHE. Such a substantial step illustrates how HHS staff are working hard during the pandemic to fulfill the needs of the EHE initiative, he noted. This dashboard—America's HIV Epidemic Analysis Dashboard (AHEAD) (https://ahead.hiv.gov/) will enable HHS to track its goals transparently. The public, including EHE grantees, will have access to the dashboard data and can hold HHS accountable for meeting its goals. To assist jurisdictions implementing the EHE initiative, CDC's EHE in Action web page describes the results of the so-called jumpstart sites—early projects funded through the HHS Minority HIV/AIDS Fund. ADM Giroir pointed out that ending HIV and addressing substance use have become harder during the pandemic. Many social determinants of health, such as employment and health insurance, are affected by the pandemic, and they also are related to risk for HIV and substance use.

In response to PACHA's advice, the RSP program was revised to better ensure that individuals can adhere to their medication regimen, among other updates to the program. ADM Giroir added that he looks forward to PACHA's suggestions on how to improve RSP enrollment. He also announced that HRSA's HIV/AIDS Bureau recently released three new notices of funding opportunities that focus on improving care and treatment coordination for Black women with HIV; building capacity to implement rapid antiretroviral initiation for improved engagement; and reducing stigma at the systems, organizational, and individual client level in the Ryan White HIV/AIDS Program.

ADM Giroir stressed that ending HIV is not solely the responsibility of OIDP. Agencies across HHS are engaged in this effort. For example, the Office of Population Affairs (OPA) made PrEP a key component of Title X family planning programs, which treat 3.5 million people each year. OPA developed a guide to assist organizational decision makers who are considering offering PrEP, as well as a companion guide that compiles examples from 10 family planning sites that have integrated PrEP. OPA created a new substance use toolkit for Title X–funded organizations, which are in a good position to screen for substance use. Furthermore, the Teen Pregnancy Program now includes prevention of sexually transmitted infections and pregnancy as dual goals. ADM Giroir noted that his office continually seeks ways to incorporate HIV prevention into the work across the agency, because ending the epidemic requires a whole-of-government—and indeed, a whole-of-society—approach.

Finally, ADM Giroir administered the oath of office to Laura Platero, J.D. He stated that he takes the makeup of PACHA very seriously, and Ms. Platero was selected not only on the basis of her excellent credentials, but also because she is the kind of "mover and shaker" that the EHE initiative needs.

Discussion

Dr. Wiesman appreciated the scope of the EHE initiative, noting that no other program has involved such a large portion of Federal government agencies.

Ms. Platero commented that she is excited to be part of PACHA and pleased that she can bring her long history of work on HIV/AIDS to bear on PACHA's deliberations. She expressed that she conducts her work in recognition of the Native Americans and American Indians she has known who passed away from HIV. She continued that she is honored to carry out this work for them, for all her ancestors, and for all those in Indian Country.

Roll Call

PACHA Executive Director B. Kaye Hayes, M.P.A., called the roll.

Acknowledgment of Upcoming Retirements

Mr. Schmid recognized two outstanding Federal public health leaders who will be retiring soon: RADM Sylvia Trent-Adams, Ph.D., RN, FAAN, OIDP Acting Director and Principal Deputy ASH, and Eugene McCray, M.D., Director of the CDC's Division of HIV/AIDS Prevention at NCHHSTP. Mr. Schmid and Dr. Wiesman described some of the accomplishments of the two officials and thanked them for their great contributions to public health. RADM Trent-Adams and Dr. McCray expressed their gratitude for opportunities to work with outstanding colleagues in the field during their careers.

Resolution Introduction and Discussion

Coronavirus (COVID-19) and the HIV Response

Mr. Schmid introduced a resolution that was drafted by the EHE and the Updated National HIV/AIDS Strategy Subcommittee. The document offers suggestions that emerged from the June 2020 PACHA meeting on steps the Federal government can take to improve HIV prevention and treatment services in the context of the pandemic. Members offered changes to ensure that—

- Tribal epidemiology centers participate in research on the effect of COVID-19 on PWH;
- the role and capacity of nurses are recognized; and
- health care workers who are at increased susceptibility for complications associated with COVID-19 have access to accommodations so they can continue their work.

Vote

The Council voted unanimously in favor of finalizing the resolution, as amended, and sending it to the ASH.

See Appendix A for the final resolution.

RSP Enrollment

Mr. Schmid introduced the resolution, which was also drafted by the EHE and the Updated National HIV/AIDS Strategy Subcommittee. The resolution offers 12 suggestions on how to increase enrollment in the RSP program, as requested by ADM Giroir. Members offered changes to ensure that—

- the role of COVID-19 in reducing access to HIV testing is acknowledged;
- IHS's pharmaceutical services (provided by the National Supply Service Center) are incorporated into the program; and
- the need for funding for education, case management, and adherence support is specified.

Vote

The Council voted unanimously in favor of finalizing the resolution, as amended, and sending it to the ASH.

See Appendix B for the final resolution.

Health Care Nondiscrimination Regulation

The resolution was introduced by Rafaelé Narváez and Justin C. Smith, M.S., M.P.H., Co-Chairs of the Stigma and Disparities Subcommittee, which drafted the resolution. It calls on HHS not to finalize a proposed rule change to Section 1557 of the Patient Protection and Affordable Care Act that PACHA believes would allow for discrimination on the basis of sexual orientation or gender identity. Members offered some minor editorial changes.

Vote

The Council voted unanimously in favor of finalizing the resolution, as amended, and sending it to the ASH.

See Appendix C for the final resolution.

Public Comments

Lauren Miller of the National Minority AIDS Council said her organization has been conducting focus groups across the country in the communities that are implementing EHE, and responses have been consistent across the board. The consensus is that safe, affordable housing is key to access to and use of health care services, medication adherence, and retention in care. She urged PACHA to consider how the EHE initiative prioritizes housing.

Ace Robinson of the National Minority AIDS Council stressed the importance of using data to drive care and track progress toward the goals of the EHE initiative. Great steps have been taken toward reducing morbidity and mortality among some populations highly impacted by HIV, but not all. Specifically, Mr. Robinson pointed out the need to address HIV incidence and morbidity in the American Indian and Alaska Native (AI/AN) populations. He called for more investment in AI/AN communities to ensure they get appropriate care so they can improve their quality of life. The continued lack of investment in AI/AN health has led these populations to distrust the purported support for addressing HIV and other illnesses. As an example, the IHS was to receive $25 million to fund activities under the EHE initiative but never received that funding.
Mr. Robinson asked PACHA to recommit to supporting Indian Country and to strengthen community-centered national plans that address the unique needs of Tribal members affected by HIV.

Tristan Schukraft of Mistr described his company's telemedicine platform, which links users to PrEP through partnerships with community-based organizations. Mr. Schukraft explained that Mistr and its partner organizations enroll thousands of people in PrEP programs, subsidize the costs of health care visits and laboratory tests, and handle the insurance paperwork to ensure that users get their prescriptions. He added that Mistr is looking for ways to collaborate with PACHA and others to build on their success.

Murray Penner of the Prevention Access Campaign and U = U commented that COVID-19 and the increased focus on the need for racial equality are reminders that HIV in the United States will persist until racial injustices are addressed. CDC estimates that only 63 percent of U.S. PWH have achieved viral suppression. Approximately 400,000 PWH are not virally suppressed and therefore cannot achieve optimal health, and many of them are people of color. The Ryan White HIV/AIDS Program demonstrates that holistic HIV health care increases viral suppression dramatically. Efforts should be made to achieve the program's 87-percent viral suppression rate in the broader community. Viral suppression helps PWH live long and healthy lives and prevents new transmission of HIV to their sexual partners. When HIV viral load is undetectable, the virus is untransmittable (known as U = U), which is the foundation for ending the epidemic and can remove stigma around PWH and HIV testing.

To improve viral suppression rates in the United States, Mr. Penner proposed the following:

- As part of EHE, HHS should conduct a national campaign that augments CDC's campaigns, similar to the RSP campaign.
- Because more than 40 percent of PWH use Medicaid services, CMS and other Medicaid agencies should be involved in EHE planning at both the Federal and State levels. State Medicaid programs should provide viral suppression data to inform local EHE plans and to help ensure that all PWH enrolled in Medicaid receive the support they need to achieve viral suppression. CMS should issue an informational bulletin to State Medicaid programs about EHE and viral suppression to help garner collaboration at the State level.
- Jurisdictions should focus on tracking engagement in care, implement immediate steps to reengage people who drop out of care, and strongly emphasize locating people out of care and helping them return. A National Center for Excellence focused on how to engage and reengage PWH in care could help jurisdictions implement and refine local programs to improve viral suppression rates.
- PWH, especially people of color, must be involved (even virtually) in designing programs that provide them the support needed to achieve viral suppression. PWH also should be hired in local jurisdictions as treatment and peer navigators to help other PWH achieve viral suppression.

See Appendix D for additional public comments submitted.

Closing Remarks from the PACHA Co-Chairs

Dr. Wiesman pointed out that the resolutions demonstrate how PACHA incorporates the input of community partners and public commenters into policy recommendations for HHS, and he added that Federal partners have been very responsive to PACHA. He noted that PACHA has focused on social determinants of health throughout its current iteration, and the pandemic has emphasized disparate effects on populations that have suffered from injustice, oppression, and discrimination for centuries. Dr. Wiesman expressed appreciation for all those working in the HIV field and underscored the continued need for policies and resources to support the work.

Mr. Schmid echoed Dr. Wiesman's comments that the resolutions are the culmination of months of work and reflect what PACHA has heard from partners and the public. Mr. Schmid and Dr. Wiesman thanked the PACHA members, presenters, participants, and organizers. The meeting adjourned at 4:55 p.m.

Appendix A: Resolution on the Impact of Novel Coronavirus on HIV Prevention & Treatment

Resolution on the Impact of Novel Coronavirus on HIV Prevention & Treatment

Whereas, the novel coronavirus (COVID-19) pandemic has greatly interrupted the delivery of healthcare in the United States, including the prevention and treatment of HIV;

Whereas, this interruption has been particularly pronounced because many HIV providers, community-based organizations and state, local, and tribal health departments or programs who have expertise in infectious diseases are directly involved in the COVID-19 response;

Whereas, the Presidential Advisory Council on HIV/AIDS (PACHA) convened on June 1–2, 2020 and heard from a broad array of stakeholders and subject-matter experts to learn of the current and expected impacts of COVID-19 on HIV prevention and treatment. Speakers included providers, people living with and at risk of HIV, state health department personnel, community-based organization leaders, and federal partners;

Whereas, PACHA also sought comments on what is needed now and in the future to ensure HIV prevention and treatment services are delivered to the people who need them and how challenges are being overcome by creatively adapting innovative practices;

Therefore, be it resolved that PACHA urges the Secretary of Health and Human Services (HHS) to take the following actions to address the current and expected impacts of COVID-19 on HIV prevention and treatment, and to improve HIV prevention and treatment activities in the future to ensure the success of the *Ending the HIV Epidemic: A Plan for America (EHE)* initiative:

1. **People living with or at risk of HIV** are struggling due to lost income and staying at home. To address emotional and financial needs, including housing, food, and income, PACHA recommends—
    a. Increased funding for the Ryan White HIV/AIDS Program, the Housing Opportunities for People living with AIDS (HOPWA) program, and the Indian Health Service that is dedicated for program recipients focusing on those areas most impacted by COVID and HIV;
    b. Continued and expanded funding for EHE.

2. **Community-based organizations** are facing financial hardship, have had to keep their doors closed and employees away, and are not able to see clients. PACHA recommends—

    a. Increased dedicated funding for organizations that receive funding from the Ryan White Program, CDC Division of HIV Prevention, and HOPWA to be used to adapt activities and practices during the COVID-19 pandemic and maintain their stability;
    b. Adjust federal and state deliverables so that organizations can continue to receive funding without meeting metrics established pre-COVID.

3. **State, local and tribal government** revenue is down, making it difficult to administer public health programs and deliver HIV prevention and treatment services. PACHA recommends—

    a. Increased dedicated funding for state, local, and tribal health departments or programs, including the Indian Health Service, to—

        i. Ensure people living with HIV (PLWH) have access to health care, including premium and copay support, the AIDS Drug Assistance Program, and other services;
        ii. Ensure people at risk of HIV have access to prevention programs, such as testing, education, surveillance and PrEP/PEP services.

4. **Telehealth** is providing opportunities for people with or at risk of HIV to interact with providers, counselors, and case managers without traveling during this period of social distancing. Telehealth has supported many PLWH to maintain their treatment adherence and continuity of care. However, telehealth is not available to all and not all HIV prevention and treatment activities can be conducted through telehealth. PACHA recommends—

    a. Federal agencies responsible for implementing HIV prevention and treatment programs continue to encourage grantees to utilize telehealth activities during the COVID-19 pandemic, and provide capacity building and technical assistance to do so;
    b. Federal agencies begin nationwide monitoring and evaluation of how HIV-related telehealth services have been implemented due to COVID-19, to inform how the use of telehealth for HIV programming can be sustained and expanded post COVID-19. Barriers that should be addressed include the lack of accessibility to broadband and technology, including smart phone devices, experienced by some PLWH and providers, Federal and State laws and regulations, privacy concerns, reimbursement, licensure, and language access;
    c. Ensure that in-person services are available when needed. Telehealth cannot replace all in-person visits. Agencies and grantees should incorporate telehealth as appropriate, including hybrid telehealth models, and allow audio-only calls for individuals without smart phone devices.

5. **HIV testing** has been dramatically reduced due to the scaling back of in-person health visits. To improve access to HIV testing during now and in the future, PACHA recommends—

    c. Federal agencies and their grantees increase the use of free or low-cost HIV self-testing to increase awareness of HIV status, initiation of PrEP/PEP, and monitoring of PrEP/PEP users;
    d. Expand the provision of STD and hepatitis self-tests to people who are offered HIV self-test kits;
    e. Expand the availability of self-collection of lab samples for the monitoring and management of HIV;

f. Evaluate opportunities for expanding HIV testing in non-traditional settings, including pharmacies, opt-out routine testing in emergency rooms, and other medical settings;
g. Evaluate opportunities for co-locating HIV testing and COVID-19 testing;
h. Ensure there is corresponding linkage to care support wherever HIV testing occurs, including the use of telehealth.

6. **Health care coverage** for a growing number of people is being reduced due to increased unemployment and there is a greater reliance on the Ryan White HIV/AIDS Program, State Medicaid programs, the Indian Health Service, and Affordable Care Act (ACA) plans. PACHA recommends—

   i. Continue and increase funding for the Ryan White HIV/AIDS Program, State Medicaid programs, and the Indian Health Service, and ensure access to ACA plans;
   j. Encourage the expansion of Medicaid in states that have not done so in order to increase health coverage for low-income people.

7. **Flexibility in the delivery of HIV services** has been granted by the Federal government to its grantees during the public health emergency, including streamlined recertifications, fewer reporting and documentation requirements, 90-day refills of prescription drugs, and mail-order delivery. PACHA recommends—

   a. HHS agencies undertake a review of the flexibilities offered during the emergency and recommend to the Secretary, after public and community input, those that should be continued into the future;
   b. Support the amendment of laws and regulations to accomplish these changes.

8. **HIV workforce,** including those in the public health, due to their expertise in infectious diseases, are being deployed to address COVID-19 and taking them away from their ongoing HIV work. PACHA recommends—

   a. Increased investment in HIV workforce and those involved in infectious diseases, build up the public health infrastructure;
   b. Mandate that State and local governments fully staff Federally-funded HIV, STD and hepatitis programs as a requirement of accepting grant funding, and have the ability to rapidly institute hiring and contracting procedures in place, along with training systems;
   c. Implement student loan forgiveness programs and continue and expand EHE funding;
   d. Increase capacity of the more than 3 million nurses in the United States to respond to HIV and infectious diseases;
   e. Ensure that health care providers who are at increased susceptibility for severe complications associated with COVID-19 are accommodated so that they can carry out their work, including through telehealth.

9. **HIV prevention** activities and programs have been difficult to carry out during the COVID-19 public health emergency, including the initiation of PrEP, conducting syringe service programs, behavioral interventions to reduce HIV risk, and sex education. PACHA recommends—

   a. Examine pharmacists' and registered nurses' initiation of PrEP, increase use of syringes services through delivery carriers/mobile vans, and condom delivery;

b. Analyze ways jurisdictions have been able to adapt the provision of HIV/STD prevention services, and provide "Best Practices" capacity-building and technical assistance to grantees;
c. Compile and promote comprehensive sex education curricula that are being delivered via virtual platforms.

10. **Health disparities and stigma** exist with COVID-19 as they do with HIV, mainly arising from the social determinants of health. PACHA recommends—

    a. Continue to address racism and other forms of systemic discrimination within HIV care systems;
    b. Provide HIV/STI/hepatitis and COVID-19 testing for the most impacted communities and identify ways to integrate these screening efforts, particularly within communities that are even more underserved during this pandemic;
    c. Implement specific stigma reduction efforts, including education, social marketing campaigns, and normalizing testing by integrating it into other health screenings;
    d. Collect and report data on HIV and COVID-19 coinfection by key demographic categories, including socioeconomic status, race, age, gender identity, and sexual orientation.

11. **Leverage opportunities from COVID-19,** including programs and infrastructure to address HIV in the future. This includes testing, contact tracing, and a workforce that is trained and available to address other infectious diseases, such as HIV and hepatitis. PACHA recommends—

    a. HHS should integrate HIV testing and COVID testing and avail, sustain, and repurpose these resources for ending HIV and hepatitis and cross-training staff.

12. **Research the impact of COVID-19 on people living with HIV,** including direct health impacts. PACHA recommends—

    a. NIH carry out research on the impact of COVID-19 among people living with HIV, including interactions with antiretroviral (ARVs), with participation by tribal epidemiology centers;
    b. Accurate and timely data on HIV/COVID outcomes;
    c. Leverage opportunities to learn from early hotspots (i.e., New York City) about HIV/COVID connections and if there is greater risk for people living with HIV;
    d. Ensure the inclusion of people living with HIV and viral hepatitis in current and future COVID-19 vaccine trials.

Appendix B: Resolution to Increase Uptake in the Ready, Set, PrEP (RSP) Program

Resolution to Increase Uptake in the Ready, Set, PrEP (RSP) Program

Whereas, the *Ending the HIV Epidemic: A Plan for America* (EHE) initiative calls for reducing new HIV infections in the United States by 75 percent in five years and by 90 percent by 2030;

Whereas, in order to meet these goals, prevention of HIV, including the uptake of Pre-Exposure Prophylaxis (PrEP), must be increased;

Whereas, in May 2019, in an effort to increase access to PrEP, Gilead Sciences, Inc. announced that it would donate to the United States government up to 2.4 million bottles of the drugs used for PrEP for uninsured people who are at risk of HIV;

Whereas, a year after this announcement, which included time to address administrative, legal and technical issues, and months of implementing an aggressive education and public relations campaign, which included naming the program **Ready, Set, PrEP (RSP)**, and the COVID-19 pandemic, which has reduced access to health care (including HIV testing), Admiral Brett Giroir, M.D., Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS), announced during the June 2020 PACHA meeting that only 891 individuals had taken advantage of **RSP**;

Whereas, to provide PrEP to more people at risk of HIV who are uninsured, Adm. Giroir asked PACHA to develop recommendations for HHS 'consideration to improve uptake in the **RSP**;

Therefore, be it resolved that PACHA recommends that the HHS Secretary implement the following actions to increase uptake in **RSP**:

1. Ensure that there is associated funding for services associated with taking PrEP, including education, provider visits, laboratory tests, case management, and adherence support, for people using **RSP** through the Centers for Disease Control and Prevention (CDC), the Human Resources and Services Administration (HRSA) Bureau of Primary Care, Indian Health Service, and other Federal agencies whose grantees provide PrEP and that there be a system in place that **RSP** users can be directly linked to them;

2. Ask that the CDC and NIH review its guidance that dictates the necessity and frequency of various provider visits and laboratory and other tests associated with taking PrEP, particularly after the approval of a new drug for the use of PrEP;

3. Continued aggressive educational outreach to potential **RSP** users about the availability of the free drug through public relations campaigns that are culturally appropriate and available in multiple languages. These efforts should be focused on communities and areas where there are high numbers of people who are uninsured and in need of PrEP, including non-Medicaid expansion states;

4. Undertake an equally aggressive educational outreach program to providers to prescribe PrEP through RSP focusing on providers located in areas where there are high number of people who are uninsured and who serve communities who are potential users of PrEP;

5. Catalogue and publicize providers who prescribe PrEP;

6. Identify **RSP** users and ask that they become spokespeople for the program;

7. Make clear that potential **RSP** users are available to all uninsured people who are at risk of HIV and immigration status is not a barrier;

8. Continue to increase the pharmacy network participating in **RSP**, with inclusion of the Indian Health Service National Supply Service Center;

9. Request dedicated funding from the Congress for **RSP** and other EHE activities for the Office of the Assistant Secretary for Health;

10. As people are tested for COVID-19, leverage the opportunity to inform uninsured people who are at risk of HIV about **RSP**;

11. Collect information on the location, race and ethnicity, sexual orientation and gender identify of **RSP** users to measure progress and tailor outreach programs and survey participants to seek answers to why participants utilize or leave the program;

12. Invest in an intensive pilot program to expand **RSP** in individual communities, and measure results and approaches that can be applied to other areas.

Be it further resolved that HHS should acknowledge that there are other mechanisms in place for uninsured individuals to receive PrEP that provide financial benefits for entities prescribing PrEP that then can be used to cover the costs of PrEP services, such as lab tests, outreach, and staff. HHS should review the various avenues through which uninsured people receive PrEP and recalibrate the potential number of individuals that might utilize **RSP.** Based on its findings, HHS may want to revise its education and public relations efforts to be more expansive.

Appendix C: PACHA 1557 Rule Resolution

PACHA 1557 Rule Resolution

Whereas, members of PACHA met with the Department of Health And Human Services (HHS) Office of Civil Rights (OCR) on September 24, 2019 to express concerns that proposed rule changes to Section 1557 of the Affordable Care Act being considered by HHS OCR could allow for discrimination against lesbian, gay, bisexual, and transgender (LGBT) persons in healthcare settings;

Whereas, HHS OCR provided a written follow-up response to our meeting on October 8, 2019 affirming OCR's assertion that "discrimination has no place in our Nation's healthcare system";

Whereas, the United States Supreme Court ruled on June 15, 2020, that Title VII of the Civil Rights Act of 1964 prohibits employment discrimination on the basis of sexual orientation or gender identity affirming that discrimination against members of the LGBT community "on the basis of sex" is against the law;

Whereas, the Administration's *Ending the HIV Epidemic* (EHE) initiative will be more successful if members of communities with greater vulnerability to HIV, especially LGBT+ communities, have access to vital health care services, including HIV prevention and treatment services, that are free of stigma and discrimination;

Whereas, implementing OCR's proposed changes could open a window for healthcare providers to discriminate against LGBT patients, which would have a deleterious impact on the health of these communities and undermine the success of the EHE;

Be it resolved, in light of the recent Supreme Court ruling and our prior conversations with OCR, PACHA urges the Secretary to apply the same definition of discrimination "on the basis of sex" to healthcare and not move forward with implementing OCR's rule changes to Section 1557 of the Affordable Care Act that are slated to go into effect on August 18, 2020.

Be it further resolved, that if OCR implements this rule change and people are denied care based on actual or perceived sexual orientation or gender identity, OCR should have a clearly defined system for reporting such instances.

Passed on August 6, 2020

Appendix D: Written Public Comments for the Presidential Advisory Council on HIV/AIDS

Public Comments for PACHA
August 6, 2020
by Murray Penner, U.S. Executive Director, Prevention Access Campaign

Thank you for this opportunity to provide comments. My name is Murray Penner and I'm the U.S. Executive Director for the Prevention Access Campaign and U=U. COVID-19 and the increased focus on the need for racial equality have provided reminders for us as we work to End the HIV Epidemic in the U.S. Both issues have once again screamed to us loud and clear that we will not end HIV in the U.S. until we address and overcome the racial injustices against Black and Brown people.

Far too many people with HIV in the U.S. are not virally suppressed. CDC estimates that 63% of people with HIV in the U.S. are virally suppressed. That means there are more than 400,000 people with HIV, many of them Black and Brown, who aren't able to achieve optimal health because their HIV is not suppressed. The reasons for this vary, but we know when people's lives are supported holistically, viral suppression increases dramatically. Look at the Ryan White Program, which touts over an 87% viral suppression rate. We should endeavor to achieve this outside of Ryan White.

Achieving viral suppression has tremendous benefits. First, viral suppression has the power to help people with HIV live long and healthy lives. Second, viral suppression prevents new transmission of HIV to sexual partners of people with HIV. We know this as Undetectable equals Untransmittable, or U=U. As Dr. Fauci says, U=U is the foundation of being able to end the epidemic. And last, U=U destigmatizes what it means to live with HIV and data show it has the power to encourage people to test for HIV.

So today, I offer several suggestions to improve viral suppression rates in the U.S.:

First, as part of EHE, HHS should conduct a national campaign that augments CDC's campaigns, similar to the Ready, Set, PrEP campaign.

Second, since over 40% of people with HIV utilize Medicaid services, CMS and Medicaid agencies should be at the table in EHE planning at both the federal and state levels. State Medicaids should provide viral suppression data to inform local EHE plans and to help ensure that all people with HIV in Medicaid receive the support they need to achieve viral suppression. CMS should issue an informational bulletin to state Medicaids about EHE and viral suppression to help garner collaboration at the state level. As Admiral Giroir discussed earlier, this would ensure a whole of government approach to EHE.

Next, jurisdictions should focus on tracking engagement in care and when someone drops out of care, immediate steps should be taken to help them return to care. There should also be a strong emphasis on locating people out of care and helping them return.

Further, a National Center for Excellence about how to engage and re-engage people with HIV into care could go a long way to help jurisdictions implement and refine local programs to improve viral suppression rates.

Finally, people with HIV, especially Black, Brown and Transgender people, MUST be at the table (even if it's virtual) in designing programs that support them to achieve viral suppression. People with HIV should also be hired in local jurisdictions to serve as treatment and peer navigators to help more people with HIV achieve viral suppression.

Thank you again for the opportunity to speak to you today.

Our Ending the Epidemic Plan Needs to Invest in PrEP—but Not Just the Cost of the Pill
https://www.thebody.com/article/ending-hiv-epidemic-plan-invest-prep-more-than-just-cost

Giffin Daughtridge, M.D.
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U.S. Secretary of Health and Human Services Alex Azar speaks at a briefing at the Department of Health and Human Services on June 26, 2020 in Washington, DC. Joshua Roberts via GettyImages

Ending the HIV Epidemic: A Plan for America (EHE) aims to end the HIV epidemic in the United States by 2030. Doing so requires a massive investment in HIV prevention efforts, largely focused on pre-exposure prophylaxis (PrEP), but this public health investment must support removing all the financial barriers to a patient being on PrEP, not just access to the medication.

Effective PrEP can be thought of as a three-legged stool. If any one of the three legs are missing, the stool falls over, and PrEP doesn't prevent HIV. The three legs are:

1. Uptake: getting people on the medication through affordable access, education efforts, and building awareness.

2. Adherence: ensuring the medication is taken consistently and correctly.

3. Persistence: ensuring the individual continues taking the medication consistently and correctly through their season(s) of risk.

To date, PrEP investments have largely focused on the Uptake leg, and this has limited PrEP's impact. The recent data on the Ready, Set, PrEP program reported at June's Presidential Advisory Council on HIV and AIDS (PACHA) meeting perfectly demonstrates this. Ready, Set, PrEP is a program set up by the pharmaceutical company Gilead Sciences and EHE to provide 200,000 free PrEP prescriptions to those who cannot afford it. At June's meeting, it was reported that only 891 people had received PrEP through the program in its first six months. A major reason why is that Ready, Set, PrEP only supports the Uptake leg of the stool, without addressing barriers to people staying on the medication, like the cost of required lab testing and clinical visits.

The slow uptake of Ready, Set, PrEP underscores the larger trend in PrEP adoption in the U.S. Since Truvada (FTC/tenofovir disoproxil fumarate) as PrEP got its Food and Drug Administration (FDA) approval in 2012, Gilead has provided access to PrEP free of charge for uninsured and underinsured patients through its Patient Assistance Program. However, only covering Uptake has led to fewer than 20% of the 1.2 million people in the country who the Centers for Disease Control and Prevention (CDC) says should be on PrEP actually taking it.

Though the PrEP drug itself (Truvada and Descovy [emtricitabine/tenofovir alafenamide] both have FDA approval for use as PrEP) is by far the most expensive element of being on PrEP (at over $20,000 per year), it is not the only cost. Being on PrEP requires a series of lab tests for HIV, sexually transmitted infections, and kidney function, which the CDC recommends be done every three months. For uninsured patients, those with a deductible or copay, or those whose lab is not in network with their insurer, these lab tests can cost the patient hundreds of dollars a year out of pocket, depending on the specifics of their plan. As a result, even though Ready, Set, PrEP, and Gilead's Patient Assistance Program are covering the Uptake leg, the PrEP stool is falling over, because patients aren't able to Persist on the medication due to these costs.

In other words, we have a drug that can prevent HIV, and we already have the political will to pay its substantial cost. **But we are failing to prevent HIV for the majority of people in this country who need it**, because we won't pay less than 5% of the drug's cost per year for lab testing.

The following three solutions could dramatically increase access to PrEP lab testing:

1. Guideline adoption and payer coverage: The United States Preventive Services Task Force (USPSTF) and CDC PrEP guidelines inform insurance coverage of lab testing. The USPSTF has given a comprehensive PrEP package—which includes the medication, clinical visits, and lab tests—an A grade, its highest recommendation. Typically, this means that insurers would then cover the medication and lab testing without copays. The advocacy work to ensure payers cover this comprehensive PrEP package is currently underway. UnitedHealthcare, one of the largest payer plans in the country, just announced they would be doing so, and it is critical that other payers follow their lead.

2. EHE and public health payments for lab testing: EHE and the CDC have extensive public health budgets for HIV prevention. This funding is often used for safety-net care for the uninsured. Allocating some of this funding specifically for PrEP lab testing could help ensure every patient has access to the tests needed to be on PrEP.

3. Expansion of payer networks with labs offering PrEP testing: Currently, LabCorp and Quest Diagnostics have a stranglehold on payer networks. Payers force patients to go to LabCorp or Quest Diagnostics, despite other labs offering a more convenient option to the patient. For example, Molecular Testing Labs (MTL) offers the entire PrEP panel in a self-collection format, which makes it easier for the patient and the provider, but MTL is blocked from getting in-network with many payers.

To truly end the epidemic, we must invest in paying for PrEP lab testing alongside our investments in the PrEP medications. Otherwise, our stool will never stand on its own, and PrEP will never live up to its potential to eradicate new HIV infections.

Giffin Daughtridge, M.D.

Giffin Daughtridge has an M.D. from the University of Pennsylvania and an M.P.A. from the Harvard Kennedy School and serves as the cofounder and CEO of UrSure, Inc., a wholly owned subsidiary of OraSure Technologies, Inc.

Jim Pickett

Jim Pickett is the senior director of prevention advocacy and gay men's health at AIDS Foundation Chicago.

WHAT IS MISTR?

MISTR offers discrete online access to PrEP, the once daily pill regimen that prevents HIV. With its' secure online HIPAA complaint platform, MISTR can determine if an individual is the right candidate for PrEP, and if so, makes PrEP affordable – if not completely free. MISTR manages everything, including, but not limited to; testing, prescribing, prior authorizations, denials and appeals, patient assistance enrollment and free monthly delivery of the medication.

MISTR is a tele-medicine platform initially focus on providing PrEP to gay men, but now also has a female focused brand, SISTR, both of which will soon be available in Spanish and offer trans-gender specific solutions.

CHALLENGE

Approved by the FDA in 2012, PrEP is a once daily pill regimen that is 99% effective at preventing HIV. As a result, in 2015, the U.S. Centers for Disease Control (CDC) launched an initiative to get 1.2 million high-risk individuals in the U.S. on PrEP to prevent HIV infection. However, as of March 2019, only 217,000 PrEP prescriptions were written in the U.S…why? There are several reasons for the lack of adoption:

- Cost of doctor visit and required labs (Average $400+)
- Time and hassle to see doctor (Average office visit is 121 minutes)
- Requirement for repeated visits
- Doctors unaware and/or lacking knowledge to prescribe PrEP
- Patients uncomfortable discussing PrEP with their doctor
- Judgement / Shaming
- Enrollment in Patient Assistance Programs too complicated
- Required Insurance pre-authorizations and appeals process confusing and daunting

SOLUTION

MISTR clients utilize a HIPAA compliant website where they answer a series of required questions, upload insurance information (if applicable), request an at-home testing kit or in-person lab appointment and consult with a physician via phone, video and/or online chat. With MISTR, there's no doctors office, no needles and no paperwork!

“The financial obstacle to getting PrEP isn’t so much the medication as is the associated costs to get the prescription.”

David Wohl
North Carolina AIDS Training and Education Center